

IB. DRAFT STATE LABORATORY ACCREDITATION

Env_____ represents a regulation number

Statutory Authority: _____

PART Env-C ____ DEFINITIONSEnv-C _____ Definitions. State

(a) "Assessor" means "assessor" as defined in Chapter 1, Appendix A of the National Environmental Laboratory Accreditation Conference (NELAC) standards.

(b) "Department" means department of environmental services.

(c) "Denial" means refusing to accredit in total, or in part, a laboratory applying for initial or renewal accreditation.

(d) "Limited inorganic chemistry" means 6 or less inorganic analytes, and does not include trace metals.

(e) "Primary accrediting authority" means the entity having the responsibility and accountability for determining a laboratory's compliance in meeting the NELAC standards.

(f) "Quality system" means "quality systems" as defined in Chapter 1, Appendix A of the NELAC standards.

(g) "Responsible party of record" means the person, however named, responsible for supervising laboratory procedures and test result reporting.

(h) "Revocation" means the total or partial removal of a laboratory's accreditation.

(i) "Secondary accrediting authority" means an entity that grants accreditation to laboratories accredited by any other National Environmental Laboratory Accreditation Program (NELAP)-recognized primary accrediting authority.

(j) "Successful participation" means receiving "acceptable" or "check for error" on all available concentrations for analytes accredited on an analyte-by-analyte basis or "pass" for analytes accredited as a group of interdependent analytes as described in chapter 2, appendix C of the NELAC standards.

(k) "Successor in interest" means any laboratory which is owned or controlled by a majority of persons owning or controlling a laboratory accredited under a previously issued certificate.

(l) "Suspension" means the temporary removal of a laboratory's accreditation in part or in total for a defined period of time.

(m) "Technical director" means a person, however named, responsible for supervising laboratory procedures and test results reporting for a particular area of the laboratory.

PART Env-_____ APPLICATIONS, FEES, CERTIFICATES, AND USE OF NELAC NAME & LOGOEnv _____ Requirements for All Laboratories.

(a) In order to request initial or renewed accreditation pursuant to _____, the applicant shall provide the department with an application on the forms specified in (e) below.

(b) On the forms, the applicant shall provide the department with the following:

(1) Date of application;

- (2) New Hampshire lab identification number, if a renewal; (NO PAGE 2)
- (3) Legal name, mailing address, street address, billing address, telephone number, and fax number of the laboratory;
- (4) Laboratory hours of operation;
- (5) Name, telephone number, extension number, and e-mail address of the laboratory contact person;
- (6) Name, telephone number, and extension of the responsible party of record and quality assurance officer;
- (7) Amount of fees due as specified by Env-_____ below;
- (8) Name and address of owners, date of incorporation, and name and addresses of principal corporate officers;
- (9) Analyte(s) for which certification is desired;
- (10) Education and experience background of responsible party of record;
- (11) List of technical directors;
- (12) Type of building housing the laboratory, space, utilities, and word processing software available;
- (13) Identification of all general use laboratory equipment;
- (14) Analytical methodology and equipment used for 9 above.
- (c) The department shall provide the laboratory with one application that shall be in WordPerfect® format and another application that shall be in Microsoft Word® format.
- (d) The department shall provide the laboratory with a hard copy of the application which shall be used by the laboratory as a reference only.
- (e) The applicant shall use a word process to complete a copy of an application in either format.
- (f) The applicant shall provide the department with a hard copy print out and a copy of the filled in electronic form as the application.
- (g) In addition to the application, a laboratory having the department, under the program known as the ____ environmental laboratory accreditation program (ELAP), as its primary accrediting authority shall provide the following:
- (1) Results of method detection limit (MDL) studies as specified in chapter 5, appendix D, section D.1.4 of the NELAC standards, including the:
- a. Name of analyte or test;
- b. Sample matrix, such as drinking water, wastewater, soil, hazardous waste, air;
- c. Date of analysis;
- d. Identification of analyst;
- e. Instrument used, including the:
1. Name of manufacturer; and

2. Model number;

f. Concentration of standards used;

g. Actual values determined;

h. Units of concentration;

i. Mean of the values;

j. Standard deviation; and

k. Calculated MDL;

) Hard copy printout and electronic copy in WordPerfect® and/or Microsoft Word® format of the quality systems manual and standard operating procedures (SOP)s as specified in Env-_____ and Env-_____; and

) College transcript of the responsible party of record.

) A signed certificate of compliance as required by section 4.1.9 of the NELAC standards:

(h) The form shall be requested from:

Program Manager,
Environmental Laboratory Accreditation Program
Department of Environmental Services

(i) The applicant shall inform the department which of the following methods the laboratory intends to use to inform all prospective New Hampshire clients of which analytes or categories it is accredited by New Hampshire to test:

) Providing a copy of the laboratory's current certificate(s) to prospective clients with all sample kits;

(2) Providing a list of tests for which the laboratory is accredited with all sample kits; or

) Using an asterisk or other mark with the appropriate legend next to the test on a price list or other literature supplied with all sample kits.

(j) A laboratory may choose to inform repeat clients of changes in certification status in writing or by sending a copy of the new certificate at the time of the change instead of informing the client each time a sample kit is sent.

(k) The applicant shall supply the department with an example of the test report that shall be provided to New Hampshire clients indicating which analytes tested were New Hampshire accredited and which tests were subcontracted, if any.

(l) The list of tests for which the laboratory is accredited by the State of New Hampshire to perform shall be indicated with the test report by one of the following:

) Using an asterisk or other mark next to the result or the name of the test with the appropriate legend on the face of the report;

(2) Providing a copy of the laboratory's current certificate(s) with all test results; or

(3) Providing a list of tests for which the laboratory is accredited with all test results.

(m) A laboratory may choose to inform repeat clients of changes in certification status in writing or by sending a copy of the new certificate at the time of the change instead of informing the client each time a test report is sent.

(n) A nonrefundable fee shall accompany all applications.

Drinking water and wastewater accreditation, this fee shall consist of:

(1) A \$----- base fee;

(2) In addition to the base fee, the nonrefundable fee shall also include the amount(s) in Table 300-1 below:

Table 300-1 Additional Fees Included in Nonrefundable Fee

<u>Accreditation Requested</u>	<u>Fee</u>
Microbiology	\$_____
Limited inorganic chemistry only	\$_____
One or 2 metals only	\$_____
Microbiology and limited inorganic chemistry	\$_____
Microbiology and one or 2 metals	\$_____
Microbiology, limited inorganic chemistry, and one or 2 metals	\$_____
Metals and/or inorganic chemistry	\$_____
Organic chemistry	\$_____
Radiological chemistry	_____
Each performance based method that must be evaluated	\$_____

) The application shall not be processed until the correct fee is received.

(q) In addition to the nonrefundable fee, the laboratory shall reimburse the state for the following costs associated with a routine assessment or follow-up inspection:

(1) Staff expenses, which shall include the time needed to:

- a. Review the application and documents supplied with the application as well as the time needed to prepare the checklist used for the assessment or inspection;
- b. Travel to and from the laboratory;
- c. Inspect the laboratory; and
- d. Prepare the report;
- e. The total amount of time needed for a. through d. shall be multiplied by the hourly rate of the inspector plus employee benefits to determine the total owed for staff expenses;

(3) Meals and lodging while on out-of-state inspections;

(4) Mileage at IRS rate;

(5) Tolls;

(6) Public transportation; and

(7) Parking.

(r) The laboratory shall be informed of the costs associated with the inspection with the assessment report required in section 3.5.6 of the NELAC standards. If accreditation is denied, revoked, or suspended based on the inspection, or the laboratory withdraws its request for accreditation, the laboratory shall pay the costs of the inspection within 30 days of receiving the assessment report. Checks and money orders shall be made payable to the _____ department of environmental services. Funds received shall be deposited in a special account maintained by the department to offset the costs of the accreditation program.

(s) A mobile laboratory not associated with a fixed based laboratory shall be considered to be a separate laboratory and shall be subject to the same application process, fees, assessments, and other requirements as any other environmental laboratory.

(t) A mobile laboratory owned by an accredited fixed based laboratory which is equipped with instrumentation to address a temporary situation, not to exceed 90 calendar days, and is performing a subset of analyses for which the parent laboratory is accredited, shall be considered an extension of the parent laboratory and shall not require separate accreditation.

(u) Individual or remote sites shall be subject to the same application process, fees, assessments, and other requirements as other environmental laboratories.

(1) A part of a laboratory that is in a building adjacent to the laboratory or on the same parcel of land owned or rented by the laboratory shall not be considered an individual or remote site.

(2) A location that is only a sample collection site shall not be considered an environmental laboratory and shall not be subject to these requirements

Env-_____ Out-of-state Laboratories Applying for Accreditation with New Hampshire as the Secondary Accrediting Authority.

(a) Any laboratory located outside of _____ applying for accreditation with _____ as the secondary accrediting authority shall comply with all provisions set forth in Env-_____.

(b) The laboratory shall also return the following with the application:

(1) A copy of the certificate(s) from its primary NELAP approved accrediting authority with specific accredited analytes and methods noted, and the expiration date clearly indicated;

(2) A copy of the on-site assessment report(s), not more than 2 years old, used to obtain the accreditation for each area accreditation is requested.

(3) A copy of the response to the on-site assessment report(s).

(c) ELAP shall mutually recognize the primary accreditation granted by any primary NELAP-approved accrediting authority for the same matrix-analyte-method analyses that ___ ELAP accredits laboratories as a primary accrediting authority.

Env-_____ Out-of-state Laboratories Applying for Accreditation with _____ as the Primary Accrediting Authority.

(a) Before applying for accreditation with _____ as the primary accrediting authority, the laboratory shall request in writing, by registered mail, an application from ELAP.

(b) The request for the application shall be made by the laboratory responsible party of record or quality assurance officer.

(c) The request shall include the number of samples analyzed for _____ clients from January 1 to December 31 of the previous year.

) Requests shall be processed in the order received by the program manager.

(e) Multiple requests received on the same day, as documented by the date on the registered letter, shall be processed in the following order:

- (1) The laboratories operated by utilities, municipal governments, state governments, or the federal government that hold property in _____;
- (2) The laboratory having the largest number of samples, rounded to the nearest 100, analyzed for State clients as in (c) above; and
- (3) The laboratory closest to the _____ border;

The program manager shall require a list from the laboratory that includes:

- (1) The name and address of their State clients;
- (2) The dates and number of analyses performed for each client; and
- (3) The number of analyses performed for metal, organic, and other multi-component analyses shall be the number of samples received multiplied by the number of analytes the instrument is calibrated for.

) The program manager shall maintain a list of applicants in the order described above.

) The program manager shall remove any laboratory from the list that cannot verify the number required in (e) (2) above.

(i) The program manager shall inform the laboratory of its order on the list within 15 calendar days of receiving the request.

(j) When the program manager determines that staff is available, the laboratory next on the list shall be sent an application.

(k) Requests postmarked before the effective date of these rules or applications not sent to the laboratory by the program manager shall be returned to the sender.

(l) Only laboratories in states or provinces that do not have a NELAC approved accrediting authority in their host state may request New Hampshire to be its primary accrediting authority.

(m) Any laboratory located outside of _____ applying for accreditation with New Hampshire as the primary accrediting authority shall comply with all provisions set forth in Env---_____.

Env-_____ Basis for Accreditation.

(a) The results of successful participation in a proficiency test (PT) study as specified in chapter 2, appendix C of the NELAC standards shall be used to determine the accreditation status of an environmental laboratory.

(b) The results of a routine assessment, follow-up inspection, or unannounced inspection as specified in Env-_____, shall be used to determine the accreditation status of an environmental laboratory.

(c) Accreditation status shall be either "Accredited" for a laboratory meeting the NELAC standards, or "Not Accredited" for a laboratory not meeting the NELAC standards, based upon the results of the assessments and/or inspections specified in (b), above, and the results of PT studies.

Env-_____ Issuance of Certificates.

(a) The certificates issued shall be valid for one year from the date of initial issuance unless suspended, revoked, or replaced in accordance with these rules.

(b) Certificates shall be returned to ___- ELAP when accreditation is partially or totally suspended or revoked or if the request for accreditation is voluntarily withdrawn.

(c) Certificates issued as replacement certificates shall be valid until the expiration date of the original certificate.

(d) Certificates shall include the following:

(1) The name, address, fields of testing, analytes, and methods of the laboratory;

(2) A statement that continued accreditation depends on successful participation in NELAP; and

(3) A statement requesting that customers verify the laboratory's accreditation status with ___- ELAP.

) ___ ELAP shall issue a new certificate whenever there are changes to the laboratory's scope of accreditation.

(f) The laboratory shall post or display its most recent certificates in a prominent place in the laboratory.

Env-C _____ Transferring Accreditation.

(a) The accreditation shall not be directly transferrable when ownership, location, a majority of the principal officers, or a majority of the local corporate management of the laboratory changes.

(b) Any change in ownership shall meet the conditions specified in section 4.1.8 of chapter 4 of the NELAC standards.

(c) The laboratory director shall inform the department in writing within 30 calendar days as to how the changes as specified in (a) above will affect the day-to-day operations of the laboratory.

(d) The laboratory shall reapply for accreditation as specified in Env-_____ within 30 calendar days of the change in ownership, location, a majority of the principal officers, or a majority of the local corporate management of the laboratory changes.

(e) The department shall reissue new certificates within 14 calendar days of receiving the application, if there is a change in name, location, or scope of accreditation. The expiration date of the new certificates shall be the same as the expiration date on the certificates before the change.

(f) The department shall reinspect a laboratory having NH ELAP as its primary accrediting authority within 60 calendar days if there are significant changes that affect the day-to-day operations.

Env- _____ - Use of NELAC/NELAP Name and Logo.

(a) An accredited laboratory shall not misrepresent its ___ ELAP accredited fields of testing, methods, analytes, or accreditation status on any document. These documents shall include laboratory test reports, catalogs, advertising, business solicitations, quotations, or other materials.

(b) When a ___ ELAP laboratory uses the ___ ELAP name and/or the NELAC/NELAP logo in laboratory test reports, catalogs, advertising, business solicitations, quotations, or other materials, the laboratory shall include the phrase "NELAP-accredited" and the laboratory's _____ identification number.

(c) The accredited laboratory shall use its NELAP certificate, NELAP accreditation status and/or the NELAC/NELAP logo only to show compliance with the NELAC standards.

(d) If accreditation is suspended, revoked, or withdrawn, the laboratory shall discontinue the use of all laboratory test reports, catalogs, advertising, business solicitations, quotations, or other materials that contain reference to their past ___ELAP accreditation.

_____ REQUIREMENTS FOR ACCREDITATION IN CHEMISTRY

Env-_____ Personnel.

(a) The laboratory shall have a responsible party of record.

)The laboratory may have one or more technical directors.

(c) A responsible party of record or technical director shall be a full-time laboratory staff member and shall supervise laboratory procedures and test result reporting.

(d) The duties of a responsible party of record or technical director shall include, but not be limited to:

(1) Monitoring standards of performance in quality control and quality assurance;

(2) Monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data;

(3) Ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory;
and

(4) Providing educational direction to laboratory staff.

(e) An individual shall not be the responsible party of record or technical director of more than one NELAP accredited environmental laboratory without written notification to the primary accrediting authority.

(f) A responsible party of record or technical director who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of responsible party of record or technical director to temporarily perform this function.

(g) If a responsible party of record or technical director is absent exceeding 65 consecutive calendar days, the accrediting authority shall be notified in writing by the responsible party of record, the quality assurance officer, or the staff member temporarily performing the function.

(h) A responsible party of record or technical director of an environmental lab engaged in chemical analyses shall meet the following qualifications:

(1) A bachelor's degree in chemical, environmental, biological sciences, physical sciences, or engineering with at least 24 college semester credit hours in chemistry;

(2) At least 2 years experience in the environmental analysis of representative inorganic or organic analytes for which the laboratory is seeking approval;

(3) If the accredited laboratory is limited to inorganic chemical analyses, other than metals analysis, the educational requirement shall be at least an earned associates degree in chemical, physical, or environmental sciences or 2 years of equivalent and successful college education with a minimum of 16 college semester credit hours in chemistry;

(4) A full time employee of a drinking water or sewage treatment facility who holds an operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements of the responsible party of record or technical director within the scope of that facility's regulatory permit;

- (5) A full time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision shall be deemed to meet the educational and experience requirements of the responsible party of record or technical director within the scope of that facility's regulatory permit; and
- (6) A person who is the responsible party of record or a technical director of a laboratory and who does not meet the educational requirements at the time these rules become effective shall be deemed to be qualified as the responsible party of record or technical director of that laboratory or any other laboratory accredited under these rules.

A masters degree may be substituted for one year of experience.

(j) A laboratory shall have a quality assurance officer or person designated as accountable for data quality as specified in section 5.4.2 (g) of the NELAC standards.

(k) The laboratory shall also meet all organizational and personnel requirements specified in section 5.4.2 and section 5.6 of the NELAC standards.

Env-C _____ - Laboratory Facilities. The laboratory facilities shall meet the requirements as specified in section 5.7 of the NELAC standards.

Env-C _____ Laboratory Equipment and Reference Materials. The laboratory equipment and reference materials shall meet the requirements as specified in section 5.8 of the NELAC standards.

Env-C _____ Analytical Methodology. The laboratory shall meet the analytical methodology requirements as specified in section 5.10.1, 5.10.2, and 5.10.2.1 and chapter 5, appendix E of the NELAC standards.

Env-C _____ Sample Collection, Handling, and Preservation. The laboratory shall meet the sample collection, handling and preservation requirements as specified in section 5.11 of the NELAC standards.

Env-C _____ Quality Assurance Requirements.

(a) The laboratory shall meet the quality assurance requirements as specified in chapter 5, appendix D, section D.1 of the NELAC standards.

(b) If the quality control requirements of chapter 5, appendix D, section D.1 and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

Env-C _____ Calibration of Instruments.

(a) The laboratory shall meet the instrument calibration requirements as specified in section 5.9 of the NELAC standards.

(b) If the requirements in section 5.9 of the NELAC standards and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

Env-C _____ Records and Data Reporting. The laboratory shall meet the records and data reporting requirements as specified in section 4.3.3, 5.12 and 5.13 of the NELAC standards.

Env-C _____ Action Response to Laboratory Results for Compliance Purpose Samples.

(a) When action response as required in Env-_____ is a designated laboratory responsibility, the proper authorities shall be promptly notified of non-compliance sample results as required by Env-_____.

(b) When the authorities are notified of non-compliance samples as required by Env-_____, the laboratory shall request that the client send a resample from the same sampling point immediately.

Env-C _____ Outside Support Services and Supplies. The laboratory shall meet the outside support and supplies requirements as specified in section 5.15 of the NELAC standards.

Env-C _____ Complaints. The laboratory shall meet the requirements for handling complaints as specified in section 5.16 of the NELAC standards.

_____ REQUIREMENTS FOR ACCREDITATION IN MICROBIOLOGY

Env-C _____ Personnel.

(a) The laboratory shall have a responsible party of record.

)The laboratory may have one or more technical directors.

(c) A responsible party of record or technical director shall be a full-time laboratory member shall supervise laboratory procedures and test result reporting.

(d) The duties of a responsible party of record or technical director shall include, but not be limited to:

(1) Monitoring standards of performance in quality control and quality assurance;

(2) Monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data;

(3) Ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory;
and

(4) Providing educational direction to laboratory staff.

(e) An individual shall not be the responsible party of record or technical director of more than one NELAP approved environmental laboratory without written notification to the primary accrediting authority.

(f) A responsible party of record or technical director who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of responsible party of record to temporarily perform this function.

(g) If a responsible party of record or technical director is absent exceeding 65 consecutive calendar days, the accrediting authority shall be notified in writing by the responsible party of record, the quality assurance officer, or the staff member temporarily performing the function.

(h) A responsible party of record or technical director engaged in microbiological or biological analyses shall meet the following qualifications:

(1) A bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of 16 college semester credit hours in general microbiology and biology.

(2) At least 2 years experience in the environmental analysis of representative analytes for which the laboratory is seeking approval.

(3) An employee of a laboratory engaged in microbiological analyses limited to total coliform, fecal coliform, and standard plate count with an associates degree in an appropriate field of the sciences or applied sciences, with a minimum of 4 college semester credit hours in general microbiology and one year experience shall be deemed to meet the educational and experience requirements of the responsible party of record or technical director.

- (4) A full time employee of a drinking water or sewage treatment facility who holds a valid plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements of the responsible party of record or technical director within the scope of that facility's regulatory permit.
- (5) A full time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision shall be deemed to meet the educational and experience requirements of the responsible party of record or technical director within the scope of that facility's regulatory permit.
- (6) A person who is the responsible party of record or a technical director of a laboratory and who does not meet the educational requirements at the time these rules become effective shall qualify as the responsible party of record or technical director of that laboratory or any other laboratory accredited under these rules.
- (i) A masters degree may be substituted for one year of experience.

College education that includes at least 2 years of equivalent and successful education, including the microbiology requirement, may be substituted for the associates degree.

- (k) The laboratory shall also meet the requirements as specified in section 5.4.2 and section 5.6 of the NELAC standards.

Env-C ____ Laboratory Facilities. The laboratory facilities shall meet the requirements specified in section 5.7 of the NELAC standards.

Env-C ____ Laboratory Equipment and Supplies. The laboratory equipment and supplies shall meet the requirements specified in section 5.8 and 5.15 of the NELAC standards.

Env-C ____ Analytical Methodology. The laboratory analytical methodology shall meet the requirements as specified in section 5.10.1, 5.10.2, and 5.10.2.1 and chapter 5, appendix E of the NELAC standards.

Env-C ____ Sample Collection, Handling, and Preservation. The laboratory shall meet the sample collection, handling, and preservation requirements as specified in section 5.11 and section 5.14 of the NELAC standards.

Env-C ____ Quality Assurance Requirements.

- (a) The laboratory shall meet the quality assurance requirements as specified in chapter 5, appendix D, section D.3 of the NELAC standards.

- (b) If the quality control requirements of chapter 5, appendix D, section D.3 and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

Env-C ____ Records and Data Reporting. The laboratory shall meet the records and data reporting requirements as specified in section 4.3.3, 5.12 and 5.13 of the NELAC standards.

Env-C ____ Action Response to Laboratory Results.

- (a) When action response as required in Env-____ is a designated laboratory responsibility, the proper authorities shall be promptly notified of non-compliance sample results as required by Env-____; and

- (b) When the authorities are notified of non-compliance samples as required by Env-Ws ____, the laboratory shall request that the client send a resample from the same sampling point immediately.

Env-C ____ Outside Support Services and Supplies. The laboratory shall meet the outside support services and supplies requirements as specified in section 5.15 of the NELAC standards.

Env-C _____ Complaints. The laboratory shall meet the requirements for handling complaints as specified in section 5.16 of the NELAC standards.

_____ REQUIREMENTS FOR ACCREDITATION FOR RADIOCHEMISTRY

Env- _____ Personnel.

- (a) The laboratory shall have a responsible party of record.
- (b) The laboratory may have one or more technical directors.
- (c) A responsible party of record or technical director shall be a full-time laboratory member shall supervise laboratory procedures and test result reporting.
- (d) The duties of a responsible party of record or technical director shall include, but not be limited to:
 - (1) Monitoring standards of performance in quality control and quality assurance;
 - (2) Monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data;
 - (3) Ensuring that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory;
and
 - (4) Providing educational direction to laboratory staff.
- (e) An individual shall not be the responsible party of record or technical director of more than one NELAP approved environmental laboratory without written notification to the primary accrediting authority.
- (f) A responsible party of record or technical director who is absent for a period of time exceeding 15 consecutive calendar days shall designate another full-time staff member meeting the qualifications of responsible party of record to temporarily perform this function.
- (g) If a responsible party of record or technical director is absent exceeding 65 consecutive calendar days, the accrediting authority shall be notified in writing by the responsible party of record, the quality assurance officer, or the staff member temporarily performing the function.
- (h) A responsible party of record or technical director of an environmental lab engaged in radiochemical analyses shall meet the following qualifications:
 - (1) A bachelor's degree in chemistry, physics, or engineering with at least 24 college semester credit hours in chemistry.
 - (2) At least 2 years experience in the radiological analysis of environmental samples.
 - (3) If the accredited laboratory is engaged in the examination of radon in air only, the educational requirement shall be at least an associates degree or 2 years of college with at least one year of experience in the measurement of radon and/or radon progeny.
 - (4) A full time employee of a drinking water or sewage treatment facility who holds a valid plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements of the responsible party of record or technical director within the scope of that facility's regulatory permit.

- (5) A full time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision shall be deemed to meet the educational and experience requirements of the responsible party of record or technical director within the scope of that facility's regulatory permit.
- (6) A person who is the responsible party of record or a technical director of a laboratory and who does not meet the educational requirements at the time these rules become effective shall qualify as the responsible party of record or technical director of that laboratory or any other laboratory accredited under these rules.

A masters or doctoral degree may be substituted for one year of experience.

- (j) The laboratory shall also meet the requirements as specified in section 5.4.2 and section 5.6 of the NELAC standards.

Env-C _____ Laboratory Facilities. The laboratory facilities shall meet the requirements as specified in section 5.7 of the NELAC standards.

Env-C _____ Laboratory Equipment and Reference Materials. The laboratory equipment and reference materials shall meet the requirements as specified in section 5.8 of the NELAC standards.

Env-C _____ Analytical Methodology. The laboratory shall meet the analytical methodology requirements as specified in section 5.10.1, 5.10.2, and 5.10.2.1 and chapter 5, appendix E of the NELAC standards.

Env-C _____ Sample Collection, Handling, and Preservation. The laboratory shall meet the sample collection, handling, and preservation requirements as specified in section 5.11 and section 5.14 of the NELAC standards.

Env-C _____ Quality Assurance Requirements.

(a) The laboratory shall meet the quality assurance requirements as specified in chapter 5, appendix D, section D.4 of the NELAC standards.

(b) If the quality control requirements of chapter 5, appendix D, section D.4 and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

Env-C _____ Calibration of Instruments.

(a) The laboratory shall meet the instrument calibration requirements as specified in section 5.9 of the NELAC standards.

(b) If the requirements in section 5.9 and the requirements in an approved method differ, the laboratory shall use the stricter of the 2 requirements.

Env-C _____ Records and Data Reporting. The laboratory shall meet the records and data reporting requirements as specified in section 4.3.3, 5.12 and 5.13 of the NELAC standards.

Env-C _____ Action Response to Laboratory Results for Compliance Purpose Samples.

(a) When action response as required in Env-_____ is a designated laboratory responsibility, the proper authorities shall be promptly notified of non-compliance sample results as required by Env-_____; and

(b) When the authorities are notified of non-compliance samples as required by Env-_____, the laboratory shall request that the client send a resample from the same sampling point immediately.

Env-_____ Outside Support Services and Supplies. The laboratory shall meet the outside support and supply requirements as specified in section 5.15 of the NELAC standards.

Env-_____ Complaints. The laboratory shall meet the requirements for handling complaints as specified in section 5.16 of the NELAC standards.

_____ PROFICIENCY TESTING

Env-C 306.01 Participation in Proficiency Testing

(a) Laboratories seeking to become accredited or to maintain accreditation shall perform analyses of PT samples for each field of testing for which NELAP accreditation is sought.

(b) Each laboratory shall have an Environmental Protection Agency (EPA) laboratory code. The EPA laboratory code shall be the EPA identification number the laboratory used for reporting results of EPA's water supply and water pollution performance evaluation studies. A laboratory without an EPA laboratory code shall apply to the EPA for a code before requesting PT samples from a NELAP approved PT provider.

(c) The laboratory shall obtain PT samples from any NELAP-approved PT provider.

(d) The results of the analyses shall be submitted to the PT provider for scoring.

(e) Laboratories shall request accreditation for a field of testing, as described in section 2.1.3 of the NELAC standards

(f) Each laboratory shall participate in at least 2 PT studies per year provided by a NELAP-approved PT Provider.

(g) The 2 studies shall be as in Table 1-2 below:

Table 1-2 Proficiency Testing Schedule

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Drinking Water Chem		X						X				
Wastewater Chem					X						X	
Drinking Water Micro		X						X				
Wastewater Micro					X						X	

(h) The samples shall be analyzed and the results returned to the PT study provider no later than 45 days from the date of sample receipt.

(i) The laboratory's management and all analysts shall handle all PT samples in the same manner as client samples.

(j) The laboratory shall utilize the same staff, procedures, equipment, facilities, and frequency of analysis for PT samples as for client samples.

(k) An analyst employed at more than one laboratory shall inform the accrediting authority in writing before analyzing any PT sample.

(l) An analyst employed at more than one laboratory shall:

(1) Declare to the accrediting authority the date on which each laboratory shall analyze the PT sample.

(2) Analyze the PT sample in only one laboratory.

(3) Analyze only the PT sample analyzed on the earliest date.

(m) No personnel of an accredited laboratory shall exchange information on PT samples results with anyone from another laboratory.

(n) The laboratory shall maintain copies of all written, printed, and electronic records pertaining to PT sample analyses for 5 years or for as long as is required by the applicable regulatory program, whichever is greater.

(o) A laboratory may participate in a make up study for analyses missed.

(p) There shall be at least one month between scheduled studies and/or any make up studies.

(q) A laboratory which seeks accreditation shall successfully complete 2 PT studies for each requested field of testing within the most recent 3 rounds attempted.

(r) An accredited laboratory shall maintain a history of at least 2 successful PT studies out of the most recent 3 PT studies attempted.

) The results of make up studies shall be included in (q) and (r) above.

Env- _____ Performance Evaluation Study Results Review.

(a) Laboratories shall review all "unacceptable" or "failed" results received from PT sample analysis and determine what caused the error and what corrective action the laboratory shall take to correct the problem.

(b) The laboratory shall document in its own records the causes and corrective action the laboratory has taken to correct the problem.

(c) The laboratory shall submit a corrective action report to ____ ELAP within 30 calendar days of receiving the results.

(d) Laboratories shall submit a corrective action report before requesting a make-up PT study.

_____ QUALITY SYSTEMS MANUAL AND STANDARD OPERATING PROCEDURES MANUAL

Env- _____ Establishment

(a) The laboratory shall establish and maintain a quality system, based upon the required elements found in chapter 5 of the NELAC standards, that shall be appropriate to the type, range, and volume of environmental testing activities it undertakes.

(b) The elements of this quality system shall be documented in the organization's quality manual as specified in Env-_____

) The quality documentation shall be available for use by all laboratory personnel.

(d) The laboratory shall define and document its policies and objectives for, and its commitment to, accepted laboratory practices and quality of testing services.

(e) Laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all concerned laboratory personnel by conducting:

(1) Internal audits as specified in section 5.5.3.1 of the NELAC standards;

- (2) Managerial reviews as specified in section 5.5.3.2 of the NELAC standards;
 - (3) Audit reviews as specified in section 5.5.3.3 of the NELAC standards; and
 - (4) Performance audits as specified in section 5.5.3.4 of the NELAC standards.
- (f) The quality assurance officer shall be responsible for maintaining a current quality control manual.

Env- _____ Quality Systems Manual.

- (a) The laboratory shall prepare and maintain a quality systems manual that meet the requirements specified in section 5.5.1 and 5.5.2 of the NELAC standards.
- (b) The quality systems manual shall represent the laboratory's normal day to day operating procedures and policies.
- (c) The standard operating procedures may be a separate document referenced in the quality systems manual.

Env- _____ Standard Operating Procedures.

- (a) The laboratory shall prepare written SOP for all laboratory activities including, but not limited to sampling, test methods, instrument operation, data generation, and corrective action.
- (b) The written SOP shall accurately describe the laboratory's procedure for the analysis of client and quality control samples.
- (c) The written SOP shall be consistent with EPA approved methodology. If the method allows modifications, the modification used by the laboratory shall be documented in the SOP.
- (d) The laboratory shall maintain a record of SOP effective dates. A copy of the SOP and the record of effective dates shall be maintained for the period of time records of the data generated by those procedures are required to be maintained.
- (e) A copy of the written SOP shall be available to all personnel that engage in that particular activity.
- (f) A written SOP shall bear the signature of the laboratory director, quality assurance officer, and supervisor of the area that prepares the SOP.
- (g) The analyst shall use only the laboratory written SOP for all laboratory activities used in the analysis of compliance samples and routine environmental samples.
- (h) The laboratory shall maintain a record of samples not analyzed by the laboratory SOP.
- (i) The record required by (h) above shall include:
- (1) Laboratory sample identification traceable to client sample identification;
 - (2) Modification(s) to the SOP;
 - (3) Reason for the modification; and
 - (4) Client authorization or acknowledgment of the modification.

Env- _____ Corrective actions.

- (a) The laboratory shall implement general procedures to be followed when departures from documented policies, procedures, and quality control (QC) have taken place.

(b) The laboratory shall document departures from documented policies, procedures, and QC and the corrective actions taken as specified in section 5.5.3.5 of the NELAC standards.

(c) Where possible, the laboratory shall report data only if all QC measures are acceptable as specified in the laboratory's policies, procedure, and QC.

(d) If a QC measure is found to be a departure from documented policies, procedures, and QC, and the data is to be reported, all samples associated with the failed QC measure shall be reported with the appropriate data qualifier(s).

Env- _____ Essential Quality Control Procedures.

(a) All laboratories shall have protocols to monitor the QC as specified in section 5.5.4 a) of the NELAC standards.

(b) All QC measures shall be assessed and evaluated on an on-going basis, and the laboratory's documented QC acceptance criteria shall be used to determine the useability of the data.

(c) The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist.

_____ ASSESSMENTS

Env- _____ Routine Assessments

(a) An on-site inspection of laboratories which have ___ ELAP as their primary accrediting authority shall take place before the issuance of accreditation.

(b) In order to maintain ___ ELAP accreditation, a laboratory which has NH ELAP as its primary accrediting authority shall be inspected for all fields of testing at least once every 2 years.

(c) A completeness and technical review of the application, quality systems manual, SOP, and any other document submitted with the application, shall take place as a part of a routine inspection.

(d) Laboratory personnel shall allow duly authorized employees of the department to enter the premises of any laboratory accredited under these rules during the laboratory's normal business hours to determine compliance with the rules.

(e) Assessors shall have access to interview any/all staff involved with activities related to the areas for which the laboratory requests accreditation.

(f) Arrangements for inspection shall be made between the department and the responsible party of record.

(g) Accreditation or renewal of laboratory accreditation shall be denied for refusing to allow an announced on-site inspection.

(h) The ___ ELAP assessment team shall use NELAC approved checklists to conduct the assessment.

Env- _____ Unannounced Inspections.

(a) If the department receives information or complaints from public officials or private citizens regarding a laboratory having ___ ELAP as its primary accrediting authority, the department shall conduct an unannounced investigation pursuant to _____, VII and (b) and (c) below.

(b) An unannounced inspection shall take place if a laboratory is suspected of conducting an illegal or deceptive practice.

(c) An unannounced inspection shall take place where laboratory records could be destroyed or altered if prior notice is given.

(d) The department shall conduct an unannounced inspection during the laboratory's normal business hours when a prior agreement between the department and the laboratory's director exists.

(e) The -- ELAP team shall use either a NELAC approved checklist or a checklist prepared by the assessor to evaluate the merits of the information or complaint.

Env-_____ Follow-up Inspections.

(a) Follow-up inspections shall take place if the deficiencies noted during a routine inspection are so numerous or serious that the laboratory no longer meets the requirements for accreditation of the laboratory in part or in whole.

) Follow-up inspections shall take place within 45 calendar days of the original assessment.

) A follow-up inspection shall take place within 60 days of a second failed PT study.

(d) A follow-up inspection to examine the laboratory facilities, records, and/or personnel shall take place in order to determine the merits of a formal appeal from the laboratory.

(e) The ___ ELAP assessment team shall use NELAC approved checklists to conduct the assessment.

(f) The laboratory may request that follow-up inspections be canceled by withdrawing the request for accreditation for the affected analyses.

Env-_____ Results of the Inspection.

(a) The accrediting authority shall issue an assessment report in both hard copy and electronic copy in WordPerfect® and/or Microsoft Word® format to the laboratory within 30 calendar days of the on-site audit.

(b) The laboratory shall inform the department in in both hard copy format and electronic copy in WordPerfect® and/or Microsoft Word® format as to how all deviations have been corrected within 30 calendar days of receiving the report.

(c) Within 30 calendar days of receipt of the corrective action report, the ___ ELAP shall inform the laboratory in writing if the response meets the NELAC standards or if the response, or a portion of the response, does not meet the NELAC standards.

(d) The laboratory shall have 30 calendar days to submit a revised corrective action report if the response, or a portion, is unacceptable.

(e) The results of any inspection, along with PT sample results and information submitted with the application, shall be used to determine whether accreditation can be granted, renewed, or denied.

_____ ACCREDITATION RENEWAL

(a) An application for accreditation renewal shall be submitted to the department annually.

(b) Applications for accreditation renewal shall be submitted to the department office not later than 30 calendar days prior to the expiration date of the current certificate and in accordance with the requirements of Env-_____ if a routine assessment is not scheduled.

(c) Applications for accreditation renewal shall be submitted to the department office not later than 120 calendar days prior to the expiration date of the current certificate, and in accordance with the requirements of Env-_____ if a routine assessment is scheduled.

_____ DENIAL, REVOCATION OR SUSPENSION

iv-_____ Denial

(a) Reasons to deny accreditation shall include:

- (1) Failure to submit a completed application within 60 days after notification of apparent errors or omissions;
- (2) Failure of laboratory staff to meet the personnel qualifications as required by the NELAC standards including those related to education, training, and experience requirements;
- (3) Failure to successfully analyze and report proficiency testing samples as required by chapter 2 of the NELAC standards;
- (4) Failure to respond to an assessment report from the on-site assessment with a corrective action report within the required 30 calendar days after receipt of the assessment report;
- (5) Failure to implement the corrective actions detailed in the corrective action report as required by the primary accrediting authority in Env-_____;
- (6) Failure to pay required fees;
- (7) Failure to pass required on-site assessment(s) as specified in Env-_____;
- (8) Misrepresentation of any material fact pertinent to receiving or maintaining accreditation; and
- (9) Denial of entry during normal business hours for an on-site assessment.

(b) A laboratory shall have 2 opportunities to correct the areas of deficiencies which results in a denial of accreditation as specified in Env-_____ (b) and (d).

(c) If the laboratory is not successful in correcting the deficiencies, the laboratory shall wait at least 6 months before again reapplying for accreditation.

(d) Upon reapplication, the laboratory shall again be responsible for all or part of the fees incurred as part of the application for accreditation.

(e) No laboratory's accreditation shall be denied without the right to due process as set forth in Env-_____.

Env-_____ Suspension.

(a) One or more of the following reasons shall result in a suspension in accordance with Env-_____:

- (1) If the primary accrediting authority finds during the on-site assessment that public, safety or health requires emergency action; or
- (2) Failure to notify the primary accrediting authority within 30 calendar days of major changes in:
 - a. Laboratory ownership;
 - b. Location;
 - c. Key personnel named on the application; or

d. Major instrumentation.

(b) A suspended laboratory shall not be required to reapply for accreditation if the causes for suspension are corrected within 6 months.

(c) A suspended laboratory shall not continue to analyze samples for the affected fields of testing for which it holds accreditation.

(d) If the laboratory is unable to correct the reason for the suspension, the laboratory's accreditation shall be revoked in total or in part.

e) No laboratory's accreditation shall be suspended without the right to due process as set forth in Env-_____, except for (f) below.

(f) Failure to complete proficiency testing studies and maintain a history of successful participation of 2 of the 3 most recent PT studies shall result in the suspension of accreditation until the laboratory has successfully participated in 2 out of the most recent PT studies. The laboratory shall not be required to reapply for accreditation if the suspension is for failure on PT studies. The suspension shall take place upon the primary accrediting body's processing of the PT results, without the right of due process.

(g) A suspension shall not exceed 6 months.

Env-_____ Revocation.

(a) One or more of the following shall result in a revocation in accordance with Env-_____:

submit an acceptable corrective action report, in response to a deficiency report or failure to implement corrective action(s) related to any deficiencies found during a laboratory assessment after submitting 2 corrective action reports as specified in Env-_____

respond with an audit corrective action report within 30 calendar days of the inspection report date;

participate in the proficiency testing program as required by chapter 2 of the NELAC standards;

(4) Submittal of proficiency test sample results generated by another laboratory as its own;

(5) Misrepresentation of any material fact pertinent to receiving or maintaining accreditation;

(6) Denial of entry by an assessor during normal business hours for an on-site assessment;

(7) Conviction of charges relating to the falsification of any report relating to a laboratory analysis; and

(8) Failure to remit accreditation fees within the time limit established by ___ ELAP.

(b) Accreditation shall be revoked for each affected field of testing where the laboratory fails 3 consecutive PT studies.

(c) After correcting the cause for revocation, the laboratory may reapply for accreditation no sooner than 6 months from the official date of revocation.

(d) No laboratory's accreditation shall be revoked without the right to due process as set forth Env-_____.

_____ DEPARTMENT ACTION TO DENY, REVOKE OR SUSPEND ACCREDITATION

Env-_____ Action to Deny, Revoke or Suspend Accreditation.

(a) Whenever the department has reason to consider denial, revocation or suspension of accreditation it shall notify the concerned laboratory by certified mail of its intent to deny, revoke or suspend as well as the circumstances which form the basis thereof.

(b) The affected party shall be given an opportunity to be heard as provided for in Env-_____ prior to any decision to deny, revoke or suspend such certification.

(c) The laboratory shall not be given an opportunity to be heard as provided for Env-_____ prior to any decision to deny, revoke or suspend accreditation due to unsuccessful participation in a PT study.

(d) The laboratory shall remain accredited with continued successful PT participation, until the laboratory has been informed by registered mail of the results of the hearing process.

Env-_____ Successor in Interest Applying for Reaccreditation. The revocation or suspension of certification shall operate to prohibit any successor in interest from applying for reaccreditation from _____ until the end of the term for which the certificate was revoked or suspended.

_____ REQUESTS FOR RECONSIDERATION

Env-_____ Requesting Reconsideration of Certification Status. A request for reconsideration shall be made in accordance with Env-_____.